REMARKS

The above-identified patent application has been reviewed in light of the Examiner's Action dated October 8, 2004. Claim 1 has been amended. Claims 15 and 16 are new. Accordingly, Claims 1-16 are now pending. As set out more fully below, reconsideration and withdrawal of the rejections of the claims are respectfully requested.

Initially, Applicants would thank the Examiner for the courtesies extended during the telephone interview held on December 7, 2004. During that telephone interview, aspects of the disclosures of various of the cited references were discussed in relation to the pending claims. In addition, potential amendments to the claims, which have generally been incorporated into new Claims 15 and 16, were discussed. No agreement regarding allowable subject matter was reached.

Claims 1, 3, 5, 6, 8 and 12 stand rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,898,586 to Jeatran et al. ("Jeatran") in view of U.S. Patent Publication No. 2004/0098204 to Milosavljevic et al. ("Milosavljevic"); Claim 2 stands rejected under 35 U.S.C. §103 as being unpatenable over Jeatran in view of Milosavljevic and further in view of U.S. Patent No. 5,675,745 to Oku et al. ("Oku") and in view of an article by Kennedy ("Kennedy"); Claims 7, 9-11, and 14 stand rejected under 35 U.S.C. §103 as being unpatentable over Jeatran in view of Milosavljevic and further in view of an article by Evans ("Evans"), and Claims 4 and 13 stand rejected under 35 U.S.C. §103 as being unpatentable over Jeatran in view of Milosavljevic and further in view of Evans. In order to establish a prima facie case of obviousness under Section 103, there must be some suggestion or motivation to modify the reference or to combine the reference teachings, there must be a reasonable expectation of success, and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP Section 2143.) It is submitted that the cited references do not teach, suggest or disclose each and every element as set forth in the claims. For example, the cited references do not teach, suggest or disclose a method according to which lists comprising sets of biological samples and checklists of the steps of procedures to be performed with respect to those samples are provided, as generally recited by the claims. In addition, Applicants note that the Office Action does not provide any suggestion or motivation for making the various proposed combinations of references, and that even if the

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proposed combinations are proper, such combinations do not teach, suggest or disclose all of the claim limitations. Accordingly, the rejections of the claims as obvious should be reconsidered and withdrawn.

Claim 1 is generally directed to a method for tracking samples of a clinical study. According to Claim 1, a first clinical study protocol comprising a plurality of procedures is defined, in which the procedures comprise steps of laboratory procedures to be performed on at least some samples comprising biological material. Samples comprising biological material are accessioned by recording identifying information in a computer implemented database. A first worklist is created by assigning a first scientist to perform at least a first procedure on a first set of samples recorded in the database. A first checklist comprising steps of at least the first procedure to be performed on the samples of the first worklist is created and the first checklist is displayed to the first scientist, wherein the first scientist performs the steps of the first checklist. Claim 1 further recites recording in the database a completion status and results of at least a portion of the steps on the first checklist. The method of Claim 1 additionally includes initiating a query of the database for a status associated with at least a first of the accession samples, and generating a report in response to the query. The report includes at least some of the completion status or results stored in the database, wherein a status of the at least a first of the accessioned samples is tracked.

Claim 6 is generally directed to a computer implemented method for tracking samples of a clinical study. According to Claim 6, a list of standard operating procedures comprising procedure steps of laboratory procedures to be performed on at least some samples of biological material is provided, as is a list of samples. Claim 6 further recites that the list of standard operating procedures is merged with the list of samples to generate a checklist for use in connection with the clinical study. In addition, a report including a status of the list of samples is displayed.

Claim 8 is generally directed to a computer implemented method for tracking samples of a clinical study. According to Claim 8, a plurality of biological samples are accessioned, and procedures to be taken with respect to the biological samples are determined. In addition, Claim 8 recites defining at least a first work group comprising at least a first of the plurality of

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biological samples, wherein the first work group comprises at least one procedure to be performed on at least one of the biological samples. The procedures each comprise a plurality of steps. As recited by amended Claim 8, the method further includes displaying the checklist, performing the steps, and recording performance of the steps in the computer as the steps are performed.

The Jeatran reference is generally directed to a method for administering clinical trial material. In particular, Jeatran attempts to reduce the wastage of medications used in clinical trials, by providing an alternative to the prior art method of conducting such trials, which according to Jeatran includes providing kits consisting of each possible dosage that may be needed by a patient during the study. (See Jeatran, col. 1, l. 64 – col. 2, l. 3.) The method discussed by Jeatran includes providing a computer means that, when contacted by an investigator, is operable to identify which of a plurality of bottles of clinical material is to be disseminated to an identified patient. Confirmation of the identity of patients and the disseminated medication can be made by having the investigator enter patient identification numbers and other information (Jeatran, col. 8, ll. 30-64), check received materials and verify that all information is present (col. 11, ll. 41-60), confirm the assignment of previously assigned medication (col. 11, ll. 64-66), and administer the patient status (col. 12, ll. 28-52). Accordingly, it can be appreciated that Jeatran is directed to controlling the distribution of medication to patients by an investigator to assist in conducting blind clinical trials, without any of the investigators, patients or sponsors knowing when or what medication or randomization changes are occurring. (Jeatran, col. 14, ll. 1-16.) However, Jeatran does not describe defining or providing a list of procedures to be performed on samples of biological material or of generating reports. Instead, Jeatran discusses providing information regarding the distribution of clinical trial materials (*e.g.*, experimental medications and placebos). Therefore, there is no teaching, suggestion or disclosure of procedures with respect to biological material or the accessioning of samples of biological material in Jeatran. In addition, Jeatran does not teach, suggest or disclose the displaying as a checklist, the recordation of a completion status of steps of a procedure, or the generation of a report to teach the status of accessioned samples.

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The Milosavljevic reference is generally directed to the selective retrieval of biological samples from an integrated repository. In particular, the Milosavljevic reference is directed to providing genomic services to a client over the Internet. However, Milosavljevic does not teach, suggest or describe presenting the steps of a procedure in the form of a checklist. Instead, Milosavljevic discusses displaying experimental data or identifiers with respect to samples. Therefore, the Milosavljevic reference does not supply elements of the claims missing from the Jeatran reference.

The Oku reference is generally directed to a method for organizing workflow using a database. In particular, Oku discusses high level timetables associated with clinical studies and standards of operation. However, Oku does not teach, suggest or disclose generating a worklist concerning at least a first procedure performed on samples associated with first and second clinical protocols. In particular, Oku does not teach, suggest or disclose presenting the steps of procedures associated with samples, recording a status or performance of those steps, or other elements missing from the cited references.

The Kennedy reference is cited for teaching assigning one person to more than one project team. However, this is not the same as creating a checklist worklist related to performing at least a particular first procedure on a set of samples that includes samples from different protocols. In addition, Kennedy does not supply elements missing from the other cited references.

The Evans reference discusses how inherited characteristics affect the efficacy and toxicity of many medications with respect to individual patients. However, Evans does not teach, suggest or disclose performing a procedure included in a checklist to determine the genotype of an individual on a sample of biological material that is included in a workgroup. Furthermore, Evans does not teach, suggest or disclose a method that includes generating a checklist of procedures to be performed on samples as claimed, or other of the elements of Claims 6 and 8 that are not described by the other cited references.

As described herein, the cited references, whether considered alone or in combination, do not teach, suggest or disclose the elements of the pending claims. Therefore, reconsideration and withdrawal of the rejections of Claims 1-14 are respectfully requested.

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New Claim 15 depends from Claim 1 and is therefore allowable for at least the same reasons that Claim 1 is allowable. In addition, new Claim 15 recites that "said recording in said database a completion status comprises recording a completion status and results of less than all of said steps of said at least a first procedure." Accordingly, Claim 15 recites a method in which some but not all of the steps within a procedure can be marked as completed. This is in contrast to the references cited in the Office Action, in that those references do not teach, suggest or describe presenting the individual steps of a procedures part of checklist, or recording a completion status with respect to those steps. Accordingly, Claim 15 should be allowed.

New Claim 16 depends from Claim 6, and therefore should be allowable for at least the same reasons that Claim 6 is allowable. In addition, Claim 16 recites displaying a report comprising displaying for each of a number of samples each of said procedure steps and the status of each of said procedure steps. As noted above, the cited prior art references do not teach, suggest or disclose presenting a number of steps for each procedure or a completion status of the steps comprising a procedure. In addition, the cited references do not teach, suggest or disclose displaying the procedure steps with respect to a number of samples. Accordingly, Claim 16 should be allowed.

The application now appearing to be in form for allowance, early notification of same is respectfully requested. The Examiner is invited to contact the undersigned by telephone if doing so would expedite the resolution of this case.

Respectfully submitted,

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